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1600-1449

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1530,0220001APPLICATION NO.  
09/580,463APPLICANT  
WHEELER, CarlFILING DATE  
May 26, 2000GROUP  
1632

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
PS	AA1	4,713,339	12/15/1987	Levinson et al.	435	240.2	01/19/1983
	AB1	4,897,355	01/30/1990	Eppstein et al.	435	240.2	01/07/1985
	AC1	4,965,196	10/23/1990	Levinson et al.	435	691	01/19/1983
	AD1	5,264,618	11/23/1993	Felgner et al.	560	224	04/19/1990
	AE1	5,334,761	08/02/1994	Gebeyehu et al.	564	197	08/28/1992
	AF1	5,459,127	10/17/1995	Felgner et al.	514	7	09/16/1993
	AG1	5,580,859	12/03/1996	Felgner et al.	514	44	03/18/1994
	AH1	5,589,466	12/31/1996	Felgner et al.	514	44	01/06/1995
	AI1	5,676,954	10/14/1997	Brigham	424	450	05/08/1995
	AJ1	5,693,622	12/02/1997	Wolff et al.	514	44	06/07/1995
PS	AK1	5,703,055	12/30/1997	Felgner et al.	514	44	01/26/1994

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
PS	AL1	WO 94/29469	12/22/1994	WIPO			Yes No
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	AN1						Yes No
	AO1						Yes No
	AP1						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

PS	AR	1	Agadjanyan, M.G., et al., "An HIV type 2 DNA Vaccine Induces Cross-Reactive Immune Responses against HIV type 2 and SIV," AIDS Res. Hum. Retroviruses 13(18):1561-1572 (December 1997).
PS	AS	1	Agadjanyan, M.G., et al., "DNA Plasmid Based Vaccination Against the Oncogenic Human T Cell Leukemia Virus Type 1," Curr. Top. Microbiol. Immunol. 226:175-192 (1998).
PS	AT	1	Altman-Hamandzic, S., et al., "Expression of $\beta$ -galactosidase in mouse brain: utilization of a novel nonreplicative Sindbis virus vector as a neuronal gene delivery system," Gene Ther. 4(8):815-822 (August 1997).

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U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
RS	AA2	5,861,397	01/19/1999	Wheeler	514	247	10/03/1996
	AB2						
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FOREIGN PATENT DOCUMENTS							
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	AL2						Yes No
	AM2						Yes No
	AN2						Yes No
	AO2						Yes No
	AP2						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
RS	AR	2	Bangham, et al., "Diffusion of Univalent Ions across the Lamellae," J. Mol. Biol. 23:238-252 (1965).
RS	AS	2	Behr, J.P., et al., "Efficient gene transfer into mammalian primary endocrine cells with lipopolyamine-coated DNA," Proc. Natl. Acad. Sci. U S A. 86(18):6982-6986 (September 1989).
RS	AT	2	Boyer, J.D., et al., "In vivo protective anti-HIV immune responses in non-human primates through DNA immunization," J. Med. Primatol. 25(3):242-250 (June 1996).

EXAMINER	DATE CONSIDERED 11/2/03
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	AP3						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
PS	AR	3	Boyer, J.D., et al., "DNA Vaccination as Anti-Human Immunodeficiency Virus Immunotherapy in Infected Chimpanzees," <i>J. Infect. Dis.</i> 176(6):1501-1509 (December 1997).
PS	AS	3	Boyer, J.D., et al., "Protection of chimpanzees from high-dose heterologous HIV-1 challenge by DNA vaccination," <i>Nature Med.</i> 3(5):526-532 (May 1997).
PS	AT	3	Davis, H.L., "Plasmid DNA expression systems for the purpose of immunization," <i>Curr. Opin. Biotechnol.</i> 8(5):635-646 (October 1997).

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	AP3						Yes No
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
DS	AR	4	Davis, H.L., et al., "DNA-based immunization against hepatitis B surface antigen (HBsAg) in normal and HBsAg-transgenic mice," <i>Vaccine</i> 15(8):849-852 (June 1997).				
DS	AS	4	Davis, H.L., et al., "Direct gene transfer in skeletal muscle: plasmid DNA-based immunization against the hepatitis B virus surface antigen," <i>Vaccine</i> 12(16):1503-1509 (December 1994).				
DS	AT	4	Davis, H.L., et al., "Immune-mediated destruction of transfected muscle fibers after direct gene transfer with antigen-expressing plasmid DNA," <i>Gene Ther.</i> 4(3):181-188 (March 1997).				
EXAMINER					DATE CONSIDERED		
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## U.S. PATENT DOCUMENTS

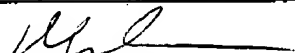
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	AO3						Yes No
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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

RS	AR	5	DeBruyne, L.A., et al., "Lipid-mediated gene transfer of viral IL-10 prolongs vascularized cardiac allograft survival by inhibiting donor-specific cellular and humoral immune responses," <i>Gene Ther.</i> 5(8):1079-1087 (August 1998).
RS	AS	5	Duzgunes, N., "Membrane fusion," in <i>Subcellular Biochemistry</i> . Roodyn, D.B., ed., Plenum Press, New York, Vol. 11, pp.195-286 (1985).
RS	AT	5	Etchart, N., et al., "Class I-restricted CTL induction by mucosal immunization with naked DNA encoding measles virus haemagglutinin," <i>J. Gen. Virol.</i> 78 ( Pt 7):1577-1580 (July 1997).

EXAMINER		DATE CONSIDERED	1/4/03
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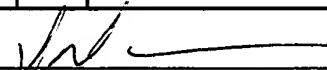
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	AP3						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
RS	AR	6	Felgner, P.L., et al., "Lipofection: A highly efficient, lipid-mediated DNA-transfection procedure," <i>Proc. Natl. Acad. Sci. U S A.</i> 84(21):7413-7417 (November 1987).
RS	AS	6	Felgner, J.H., "Separation and Quantitation of Cationic Liposome Components by High Performance Liquid Chromatography with Evaporative Light-Scattering Detection," <i>Pharm Res.</i> 14(9):1269-1271 (September 1997).
RS	AT	6	Felgner, P.L., "Nonviral Strategies for Gene Therapy," <i>Sci. Am.</i> 276:102-106 (June 1997).

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
25	AR	Z	Fukunaga, M., et al., "Liposome Entrapment Enhances the Hypocalcemic Action of Parenterally AdministeredC," <i>Endocrinology</i> 115(2):757-761 (August 1984).
25	AS	Z	Gramzinski, R.M., et al., "Immune Response to a Hepatitis B DNA Vaccine in Aotus Monkeys: A Comparison of Vaccine Formulation, Route, and Method of Administration," <i>Mol Med.</i> 4(2):109-118 (February 1998).
25	AT	Z	Gregoriadis, G., et al., "Liposome-mediated DNA vaccination," <i>FEBS Lett.</i> 402(2-3):107-110 (February 1997).

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
RS	AR	8	Hartikka, J., et al., "An Improved Plasmid DNA Expression Vector for Direct Injection into Skeletal Muscle," <i>Human Gene Ther.</i> 7(10):1205-1217 (June 1996).
LS	AS	8	Heppel, J., et al., "Development of DNA vaccines for fish: vector design, intramuscular injection and antigen expression using viral haemorrhagic septicaemia virus genes as model," <i>Fish and Shellfish Immunol.</i> 8:271-286 (1998).
RS	AT	8	Horn, et al., "Cancer Gene Therapy Using Plasmid DNA: Purification of DNA for Human Clinical Trials," <i>Human Gene Ther.</i> 6:656-573 (1995).

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	AO3						Yes No
	AP3						Yes No


OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
25	AR	2	Ishii, N., et al., "Cationic Liposomes A Strong Adjuvant for a DNA Vaccine of Human Immunodeficiency Virus Type 1, " <i>AIDS Res. Hum. Retroviruses</i> 13(16):1421-1428 (November 1997).
25	AS	2	Kim, S., et al., "Preparation of Multivesicular Liposomes," <i>Biochim. Biophys. Acta</i> 728:339-348 (1983).
25	AT	2	Klavinskis, L.S, et al., "Mucosal immunization with DNA-liposome complexes," <i>Vaccine</i> 15(8):818-820 (June 1997).
EXAMINER <i>me</i>			DATE CONSIDERED <i>1/9/03</i>
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	AP3						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
PS	AR	10	Klavinskis, L.S., et al., "Intranasal Immunization with Plasmid DNA-Lipid Complexes Elicits Mucosal Immunity in the Female Genital and Rectal Tracts," <i>J. Immunol.</i> 162(1):254-262 (January 1999).
PS	AS	10	Lodmell, D.L., et al., "Gene gun particle-mediated vaccination with plasmid DNA confers protective immunity against rabies virus infection," <i>Vaccine</i> 16(2-3):115-118 (January-February 1998).
PS	AT	10	Lodmell, D.L., et al., "DNA immunization protects nonhuman primates against rabies virus," <i>Nature Med.</i> 4(8):949-952 (August 1998).

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RS	AR	11	Mayer, L.D., et al., "Vesicles of variable sizes produced by a rapid extrusion procedure," <i>Biochim. Biophys. Acta.</i> 858(1):161-168 (June 1986).
1	AS	11	Mayhew, E., et al., "Characterization of Liposomes Prepared Using a Microemulsifier," <i>Biochim. Biophys. Acta.</i> 775(2):169-174 (August 1984).
RS	AT	11	Nishizawa, et al., "Anion Recognition by Urea and Thiourea Groups: Remarkably Simple Neutral Receptors for Dihydrogenphosphate," <i>Tetrahedron Lett.</i> 36(36):6483-6486 (1995).

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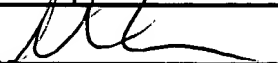
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KS	AR	12	Okada, E., et al., "Intranasal Immunization of a DNA Vaccine with IL-12- and Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF)-Expressing Plasmids in Liposomes Induces Strong Mucosal and Cell-Mediated Immune Responses Against HIV-1 Antigens," <i>J. Immunol.</i> 159(7):3638-3647 (October 1997).
I	AS	12	Olson, F., et al., "Preparation of Liposomes of Defined Size Distribution by Extrusion Through Polycarbonate Membranes," <i>Biochim. Biophys. Acta.</i> 557(1):9-23 (October 1979).
PJ	AT	12	Qin, Y.J., et al., "Gene Suture--A Novel Method for Intramuscular Gene Transfer and its Application in Hypertension Therapy," <i>Life Sci.</i> 65(21):2193-2203 (1999).

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RS	AR	13	Sambrook, et al., in <i>Molecular Cloning. A Laboratory Manual</i> , 2 <sup>nd</sup> ed., Cold Spring Harbor Laboratory Press, p. A-2 (1989).
1	AS	13	Sasaki, S., et al., "Monophosphoryl Lipid A Enhances Both Humoral and Cell-Mediated Immune Responses to DNA Vaccination Against Human Immunodeficiency Virus Type 1," <i>Infect. Immun.</i> 65(9):3520-3528 (September 1997).
RS	AT	13	Sasaki, S., et al., "Adjuvant effect of Ubenimex on a DNA vaccine for HIV-1," <i>Clin. Exp. Immunol.</i> 111(1):30-35 (January 1998).

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	AP3						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

RS	AR	14	Sasaki, S., et al., "Induction of Systemic and Mucosal Immune Responses to Human Immunodeficiency Virus Type 1 by a DNA Vaccine Formulated with QS-21 Saponin Adjuvant via Intramuscular and Intranasal Routes," <i>J. Virol.</i> 72(6):4931-9 (June 1998).
1	AS	14	Schrijver, R.S., et al., "Immunization of cattle with a BHV1 vector vaccine or a DNA vaccine both coding for the G protein of BRSV," <i>Vaccine</i> 15(17-18):1908-1916 (December 1997).
RS	AT	14	Stephan, D.J., et al., "A New Cationic Liposome DNA Complex Enhances the Efficiency of Arterial Gene Transfer <i>In Vivo</i> ," <i>Human Gene Ther.</i> 7(15):1803-1812 (October 1996).

EXAMINER	DATE CONSIDERED 1/4/07
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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 1530.0220001	APPLICATION NO. 09/580,463
	APPLICANT WHEELER, Carl	
	FILING DATE May 26, 2000	GROUP 1632

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3						
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3						Yes No
	AM3						Yes No
	AN3						Yes No
	AO3						Yes No
	AP3						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
PS	AR	15	Strauss, J.K., et al., "DNA bending by hexamethylene-tethered ammonium ions," <i>Proc. Natl. Acad. Sci. U S A.</i> 93(18):9515-9520 (September 1996).
1	AS	15	Szoka, F., et al., "Procedure for preparation of liposomes with large internal aqueous space and high capture by reverse-phase evaporation," <i>Proc. Natl. Acad. Sci. U S A.</i> 75(9):4194-4198 (September 1978).
RJ	AT	15	Ulmer, J.B., et al., "Heterologous Protection Against Influenza by Injection of DNA Encoding a Viral Protein," <i>Science</i> 259(5102):1745-9 (March 1993).

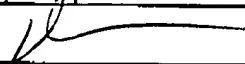
EXAMINER	DATE CONSIDERED
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	AP3						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
PS	AR	16	Ulmer, J.B., et al., "DNA Vaccines for Bacteria and Viruses," <i>Adv. Exp. Med. Biol.</i> 397:49-53 (1996).
I	AS	16	Ulmer, J.B., et al., "DNA vaccines," <i>Curr. Opin. Immunol.</i> 8(4):531-536 (August 1996).
PS	AT	16	Ulmer, J.B., et al., "Generation of MHC class I-restricted cytotoxic T lymphocytes by expression of a viral protein in muscle cells: antigen presentation by non-muscle cells," <i>Immunology</i> 89(1):59-67 (September 1996).

EXAMINER 	DATE CONSIDERED 1/9/03
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	AP3						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

PS	AR	17	Ulmer, J.B., et al., "Toward the development of DNA vaccines," <i>Curr. Opin. Biotechnol.</i> 7(6):653-658 (December 1996).
/	AS	17	Vahlsing, H.L., et al., "Immunization with plasmid DNA using a pneumatic gun," <i>J. Immunol. Methods</i> 175(1):11-22 (September 1994).
PS	AT	17	Vanderzanden, L., et al., "DNA Vaccines Expressing either the GP or NP Genes of Ebola Virus Protect Mice from Lethal Challenge," <i>Virology</i> 246(1):134-44 (June 1998).

EXAMINER	DATE CONSIDERED 1/9/03
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	AP3						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

PS	AR	19	Yokoyama, M., et al., "DNA immunization: Effects of vehicle and route of administration on the induction of protective antiviral immunity," <i>FEMS Immunol. Med. Microbiol.</i> 14(4):221-230 (July 1996).
1	AS	19	
PS	AT	19	

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	AO3						Yes No
	AP3						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
PS	AR	18	Wang, B., et al., "Mucosal immunization with a DNA vaccine induces immune responses against HIV-1 at a mucosal site," <i>Vaccine</i> 15(B):821-825 (June 1997).
/	AS	18	Wheeler, C.J., et al., "A novel cationic lipid greatly enhances plasmid DNA delivery and expression in mouse lung," <i>Proc. Natl. Acad. Sci. U S A.</i> 93(21):11454-11459 (October 1996).
RS	AT	18	Wheeler, C.J., et al., "Converting an alcohol to an amine in a cationic lipid dramatically alters the co-lipid requirement, cellular transfection activity and the ultrastructure of DNA-cytosol complexes," <i>Biochim. Biophys. Acta</i> 1280(1):1-11 (April 1996).

EXAMINER	DATE CONSIDERED 1/9/03
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	

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FORM PTO-1449  <u>FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 1530.0220001	APPLICATION NO. 09/580,463
	APPLICANT Wheeler, Carl J.	
	FILING DATE May 26, 2000	GROUP 1632

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
RS	AB2	2,368,208	01/30/1945	Epstein et al.	260 554	404.5 106	12/16/1940
	AC2	3,265,719	08/09/1966	Cowen et al.	260 554	404 110	12/28/1959
	AD2	4,864,060	09/05/1989	Karalis et al.	564	292	08/31/1987
	AE2	5,049,386	09/17/1991	Epstein et al.	424	427	05/15/1990
	AF2	5,068,431	11/26/1991	Karalis et al.	564	301	05/15/1989
	AG2	5,144,060	09/01/1992	Morita et al.	560	170	08/15/1990
RS	AH2	5,279,833	01/18/1994	Rose	424	450	04/04/1990
	AI						
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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
RS	AM1	WO 00/27795	05/18/2000	WIPO			Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR		
RS	AS	19	Barnfield, C., et al., "The Cellular Basis of Immune Induction at Mucosal Surfaces by DNA Vaccination," in <i>Development and Clinical Progress of DNA Vaccines</i> . Dev. Biol. Stand., Brown, F., et al., eds., Basel Karger 104:159-164 (2000).
RS	AT	19	Felgner, J.H., et al., "Enhanced Gene Delivery and Mechanism Studies with a Novel Series of Cationic Lipid Formulations," <i>J. Biol. Chem.</i> 269:2550-2561 (1994).

EXAMINER 	DATE CONSIDERED 6/27/02
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FORM PTO-1449 <u>FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</u>				ATTY. DOCKET NO. 1530.0220001		APPLICATION NO. 09/580,463	
				APPLICANT Wheeler, Carl J.			
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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
R8	AR	20	Menger, F.M., and Littau, C.A., "Gemini Surfactants: A New Class of Self-Assembling Molecules," <i>J. Am. Chem. Soc.</i> 115:1003-10090 (1993).
R1	AS	20	Nabel, G.J., et al., "Immunotherapy of Malignancy by <i>In Vivo</i> Gene Transfer into Tumors," <i>Hum. Gene Ther.</i> 3:399-410 (1992).
R5	AT	20	Norman, J., et al., "Adjuvants for Plasmid DNA Vaccines," in <i>Methods Mol. Med.</i> Vol. 29, <i>DNA Vaccines: Methods and Protocols</i> , Lowrie, D.B. and Whalen, R.G., Humana Press Inc., Totowa, N.J., pp. 185-196 (1998).

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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
RS	AR	21	Rosenthal, A.F., and Geyor, R.P., "A Synthetic Inhibitor of Venom Lecithinase A," <i>J. Biol. Chem.</i> 235:2202-2206 (1960).
RS	AS	21	Solodin, I., and Heath, T.D., "Synthesis of Novel Cationic Lipids with a Guanidine Group. Cationic Lipids 3," <i>SYNLETT</i> (7):617-618 (1996).
RS	AT	21	Solodin, I., and Heath, T.D., "Synthesis of Amphiphilic Piperidinium Derivatives. Cationic Lipids 4," <i>SYNLETT</i> (7):619 (1996).

EXAMINER	DATE CONSIDERED <u>7/6/03</u>
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FORM PTO-1449

## FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1530.0220001APPLICATION NO.  
09/580,463APPLICANT  
Wheeler, Carl J.FILING DATE  
May 26, 2000GROUP  
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## U.S. PATENT DOCUMENTS

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

PS	AR	22	Solodin, I., and Heath, T.D., "Synthesis of Amphiphilic Derivatives of N-Methyldiethanolamine. Cationic Lipids 5," SYNLETT (7):620 (1996).
	AS		
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